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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/09/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/650,339

Applicant(s)

EPSTEIN ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10-13, 15-18, 20-26, 28-31, 33-36 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 13, 28-30, 36, 48-53 and 56-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 11, 12, 15-18, 20-26, 31, 33-35, 44-47, 54, 55 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-3, 5-8, 10-13, 15-18, 20-26, 28-31, 33-36, 44-59 are pending. Claims 1-3, 8, 10-12, 15-18, 20-26, 31, 33-35, 44-47, 54, 55 are considered on the merits. Claims 5-7, 13, 28-30, 36, 48-53, 56-59 are withdrawn from consideration as being drawn to a non-elected invention. Claims 4, 9, 14, 19, 27, 32, 37-43, 60 and 61 have been canceled.

Group I, drawn to a composition and a kit for cell culture medium has been elected in paper #6.

The elected species under examination is a hydroxypyridine derivative.

Therefore, the elected group is examined to the extent that it reads on a cell culture medium composition comprising a hydroxypyridine derivative.

A hydroxypyridine derivative, which is the elected species, is interpreted to mean that it must at the minimum contain a hydroxy group on a pyridine core, in the absence of a precise definition in the specification.

Claim Rejections – 35 USC § 112

Claims 1-3, 8, 11, 12, 15-18, 20-24, 31 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 3-hydroxy-2-pyridinemaltol, which is not a known compound. Please note that there is no hydroxypyridine compound in claim 1 as now pending.

Claim 24 recites 3-hydroxy-2-pyridineethyl maltol, which is not a known compound.

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Please note that 3-hydroxypyrid-2-one is the same compound as 3-hydroxy-2(1H)-pyridone. Please delete one in both claims 8 and 31. See CA Registry [U].

Please note that nicotinic acid-N-oxide does not have a hydroxy group and it is thus, misclassified as a hydroxypyridine derivative in claims 8 and 31. See CA Registry [V].

Claim Rejections – 35 USC § 102

Claim 8, 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chenoufi *et al.* [W] or Ward *et al.* [Y].

The claims are directed to a serum free culture medium comprising a transition metal or a complexing compound listed in the claim.

On page 431, last line, of Chenoufi *et al.*, the composition of CP20 and serum-free medium is disclosed.

Ward *et al.* disclose the composition comprising Waymouth's Medium and hydroxypyridine compounds, see page 191 and Table 1. Waymouth's medium is a defined medium and also has FeSO₄ as a component.

Claim 24-26, 31, 34, 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gaut *al.* [X].

The claims are directed to composition comprising a cell culture medium and a hydroxypyridine derivative selected from the group consisting of 2-hydroxypyridine-N-oxide and others.

Gaut *et al.* disclose 2-hydroxynicotinic acid in a medium. Please note that the independent claim does not require a transition metal. In the dependent claims, if a transition metal were present, it would be iron, but it is not required to be present.

Claims 31, 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,328,913, Murad *et al.* [A].

The claims are directed to composition comprising a cell culture medium and a hydroxypyridine derivative selected from the group consisting of 2-hydroxypyridine-N-oxide and others.

Murad *et al.* exemplifies the composition of 2-hydroxypyridine-N-oxide in DMEM with calf serum (Table I) and cells. DMEM is a standard cell culture media which contains at least one transition element such as Fe^{+3} , see Gibco Catalog [U]. Since 2-hydroxypyridine-N-oxide is a known chelator, see Sun *et al.* [V] or Kontoghiorghes [X], it is inherent in the nature of this molecule as with other molecules termed chelators, to complex or coordinate with transition metals and form an equilibrium between complex and free transition metals, when in solution with such metals. Thus, the composition of Murad *et al.* would inherently contain both free Fe^{+3} and the complex of 2-hydroxypyridine-N-oxide and Fe^{+3} . The citations [U], [V] and [AT3] merely show inherent ingredients and properties of elements found in the prior art citation of Murad *et al.*

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landschultz *et al.* [W] or US 5,328,913 [A].

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The claims are directed to a kit composition comprising a) a cell culture media and a cell, b) a transition metal binding compound or a transition element complex.

Claim 45 and 46 do not require the presence of the transition element since the independent claim is in the alternative, but merely state that if an element were present it would be iron, etc..

Landschultz *et al.* disclose a composition comprising ferric pyridoxal isonicotinoyl hydrazone in a medium for culturing cells.

US 5,328,913 has been discussed above.

The separation of the composition of cells, medium and isonicotinoyl hydrazone into two components would have been obvious when Figure 3 of Landschultz *et al.* was examined because the first point of the curve of Figure 3, shows cells + medium which is component A of the claimed composition and the other points on the curve show cells + medium + isonicotinoyl hydrazone, component B of the claimed composition. Thus, the separation of these components is clearly shown in the Figure. Further, mere separation or division of a known composition of US 5,328,913 or Landschultz *et al.* into components which are meant to be combined prior to usage is obvious in the absence of unexpected result due to separation of the components.

Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday, Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.



Sandra Saucier
Primary Examiner
Art Unit 1651
October 8, 2003